

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,

Plaintiff,

V.

No. 20-cv-11548-NMG

TEVA PHARMACEUTICALS USA, INC., and

TEVA NEUROSCIENCE, INC.,

Defendants.

THE UNITED STATES' OPPOSITION TO
TEVA'S MOTION FOR LEAVE TO FILE AN AMENDED ANSWER

The Court should deny defendants Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc.’s (collectively, “Teva”) Motion for Leave to File an Amended Answer (ECF No. 121). Teva seeks to invoke an advice of counsel defense after the close of fact discovery and contrary to a specific order of this Court. On June 15, 2022, Teva specifically stated it would not invoke an advice of counsel defense. ECF No. 92-6. Teva has identified no new information concerning its alleged advice of counsel defense, and its post-discovery assertion of the defense would inherently and significantly prejudice the government.

The government specifically foresaw the possibility that Teva would engage in gamesmanship regarding its decision whether to invoke, which is why it (i) requested that the Court set a deadline by which Teva would be required to invoke, and (ii) made the topic the subject of its first interrogatory in this case, served over a year ago. After Teva ignored its first deadline of May 19, 2022, *see* ECF No. 50, the Court specifically and explicitly ordered Teva to decide by June 15, 2022 whether it would invoke an advice of counsel defense, for the exact reasons that Teva's Motion should now be denied:

When is discovery to be completed by? The end of September, right? There's going to be depositions after this production of documents. It doesn't sound like we're dealing with rocket science here. Why can't we say 30 days for the decision as to whether or not you're going to invoke the defense

It seems to me we're now three or four months away from [the] fact discovery deadline and the government doesn't have the necessary material for them to prepare for depositions yet. . . .

What do you have to learn before you decide as to whether or not you're going to invoke a defense of advice of counsel or good faith reliance? It puzzles me. . . . They're people that either now or did work for Teva, right? It's on your side of the V that your problem is present, correct? . . .

June 15 we're going to decide whether or not you're going to invoke the defense. July 15 you're going to produce all the documents. If you can't do that, then file a motion, and you better have good reasons as to why you can't do this. This has been six months now and we're still in the discovery phase, and we decided on a firm date, that's September 30, that was going to be the conclusion of fact discovery. You haven't convinced me that there's any good reason why you can't do it.

ECF No. 128 (Tr. or May 19, 2022 Hearing) at 8:1-6; 9:14-17; 10:11-24; 11:6-17.

Seventeen depositions have now been completed without any reference to the defense or any privileged documents available to examine or cross-examine the statements of those witnesses. Re-opening discovery would require the production of thousands of additional documents (the scope of which will be subject to extensive briefing on Teva's proposed selective waiver, as discussed below), revision of interrogatory responses by Teva, re-opening the depositions of all Teva witnesses, and conducting additional depositions of Teva lawyers—who were not listed on Teva's disclosures—and additional non-attorney Teva employees who communicated with Teva's lawyers. Teva's counsel withheld at least 11,534 documents on privilege grounds and consistently raised privilege objections throughout discovery—in response to requests for production and interrogatories and at depositions. Teva's invocation of advice of

counsel at this late stage would substantially burden both the Parties and the Court and likely delay trial.

Furthermore, Teva's stated reason for attempting to invoke an advice of counsel defense at this time—the unavailability of a fact witness (the "Witness") who Teva's counsel has represented since at least 2018, and who Teva never sought to depose—does not justify the relief it seeks. The Witness was not going to testify regarding Teva's advice of counsel defense, since Teva was not asserting that defense and was withholding privileged communications. As Judge Woodlock stated in *United States ex rel. Kieff v. Wyeth*, 03-CV-12366 (D. Mass.), regarding an attempt to invoke advice of counsel after the close of discovery:

[Y]ou make your strategic judgments. A strategic judgment was made during the course of this case to proceed with attorney-client privilege. . . . We have got a trial date. You made a choice. You are stuck with it.

Ex. 21, January 8, 2016 Hearing, p 58. Even if Teva intended to rely on this witness to support a good faith defense at trial, the unavailability of this witness does not support Teva's belated invocation of a separate advice of counsel defense. Teva also made the strategic decision not to depose or otherwise record the allegedly indispensable testimony of this witness, and to put off the Witness's deposition for months after the government requested dates for the deposition.

Teva's alleged reliance on the Witness to support a good faith defense is also inconsistent with its discovery responses and the record in this case. The United States issued specific interrogatories to Teva concerning the basis for its alleged good faith defense. ***Teva's response does not mention the Witness.*** See Ex. 1, Teva's Responses and Objections to the United States' Second Set of Interrogatories at p 8-11 (Resp. to Interrog. 16/17). Teva's response is limited to publicly available and external documents, including public HHS-OIG guidance documents and contracts with copay assistance foundations. Teva fails to identify any internal Teva

interpretations of these documents—in fact, it does not mention any internal Teva communications or documents whatsoever. *Id.* Teva accordingly has failed to identify any contemporaneous good faith belief at Teva, what the basis for that belief was, or any individuals at Teva who held that belief. *Id.* As such, even if the Witness could have supported such a defense (which is implausible for the reasons discussed in Section III.C, *infra*), Teva’s discovery responses were deficient, evasive, and precluded adequate discovery into its supposed good-faith defense—and thus represent another basis on which the Court should deny Teva’s Motion.

Teva is not unfairly prejudiced by strategic decisions it carefully made over six months ago. *See* May 19 Hearing at 6:25-7:3 (“As to the advice of counsel for defense, we have undertaken a significant investigation to date. There’s a very important decision for our client on whether it will, in fact, waive privilege”) and 10:25-11:2 (“I would hope that we would be able to get in touch with the folks that we feel that we need to get in touch with shortly.”). The Court should deny Teva’s Motion.

I. Factual Background

Teva has been investigating its advice of counsel defense for years. The government first subpoenaed Teva regarding copay donations in March 2017. *See* Ex. 2. In response to that subpoena, Teva withheld 9,124 documents listed on a 408-page privilege log, spanning seven years and involving many lawyers. Ex. 3 (privilege log dated August 13, 2019). In 2019, Teva asserted privilege in response to interrogatories pursuant to a Civil Investigative Demand (“CID”), including interrogatories that would have required Teva to disclose the names of any attorneys who approved or authorized its contributions. *See* Ex. 4 (Teva CID Interrogatory Answers dated November 13, 2019) at Gen. Obj. 3 and Interrog. 3. Teva continued to claim privilege and withhold information during under-oath CID examinations that followed.

Once litigation began, Teva refused to say whether it was claiming advice of counsel until it was ordered to do so by the Court. The government's Interrogatory No. 1, served on November 11, 2021, required Teva to state whether it was invoking "any defense based on advice of counsel," and if so, the basis for that defense, including all documents and communications concerning any such advice. *See* Ex. 5 at 4. Similarly, the government's first set of requests for production, also served on November 11, 2021, expressly required Teva to produce all communications relating to its advice of counsel defense. *See* Ex. 6 at p. 6 (Req. 5). In response to those document requests, Teva produced another, 148-page privilege log on July 15, 2022, listing 2,410 fully-withheld documents¹ involving many lawyers and spanning a period from 2005 to 2017. Ex. 7.

Teva repeatedly delayed its decision concerning a potential advice of counsel defense, claiming it was conducting a thorough investigation to make an informed decision. In a joint status report filed on December 16, 2021, Teva stated that it "will take the necessary steps before May 19, 2022 [*i.e.*, the next status conference] to make an informed and good-faith decision on whether it will assert an advice of counsel or good faith reliance on counsel defense at that time." ECF No. 50 at 1. But two days before the May 19 Hearing, Teva emailed the government to state that even though it "has conducted an investigation into whether it has a good faith basis to assert an advice of counsel defense in the DOJ's patient assistance litigation," its investigation was ongoing, and it could not yet state whether it would invoke the privilege. *See* Ex. 8 (Email dated May 17, 2022). Further, Teva proposed to eliminate any deadline for it to invoke an advice of counsel defense. *Id.*

¹ The log also listed 2,238 additional "mixed-privilege families."

At the May 19 Hearing, the Court questioned the basis for Teva's delay in determining whether to invoke, and ordered Teva to make its decision by June 15, 2022. *See* May 19 Hearing at 11:6-14 ("June 15 we're going to decide whether or not you're going to invoke the defense. You haven't convinced me that there's any good reason why you can't do it.").² The Court also recognized that Teva's failure to produce documents responsive to the government's documents requests—which had been served over six months prior—was delaying depositions. *Id.* at 9:14-17 ("It seems to me we're now three or four months away from fact discovery deadline and the government doesn't have the necessary material for them to prepare for depositions yet."). The Court ordered Teva to produce responsive documents by July 15, 2022, so that depositions could move forward. *Id.* at 11; ECF No. 61.³ Incredibly, Teva later took the position that the Court had ordered it to produce only documents relevant to any advice of counsel defense by July 15, and that there was no deadline for it to produce other responsive documents—a dispute that required the Court to confirm its order. *See* Ex. 10 (Email dated May 24, 2022).

Finally, having been ordered to do so, on June 15, 2022, Teva notified the government that it would not seek to invoke an advice-of-counsel defense:

On behalf of Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. ("Teva"), in accordance with the Court's May 19, 2022 order (ECF No. 61) in the above-referenced matter, **we write to advise you that Teva will not invoke the advice of counsel defense in this matter.**

² Teva told the Court it has "undertaken a significant investigation" of its advice of counsel defense. *Id.* at 6:25-7:1; *see also* Ex. 8 (Teva's counsel stating, "Teva has conducted an investigation into whether it has a good faith basis to assert an advice of counsel defense in the DOJ's patient assistance litigation.").

³ On the July 15 deadline—eight months after the requests were served and with depositions imminent—Teva produced 73,707 documents totaling 374,987 pages. Ex. 22 (July 15, 2022 letter).

ECF No. 92-6 (emphasis added). Five months later, on November 15, 2022, after the September 30, 2022 deadline for the completion of written fact discovery and following sixteen of seventeen fact depositions taken in this case, Teva moved to invoke an advice of counsel defense and proposed the selective waiver discussed below.

Critically, at no point in time between the government’s filing its Complaint in August 2020, until November 4, 2022, *i.e.*, the period including Teva’s “significant investigation” of its advice of counsel defense, did Teva notice the now purportedly unavailable Witness’s deposition, despite Teva’s characterization of the Witness’s testimony now as “nearly irreplaceable.” ECF No. 121 at 8. Similarly, as the government understands it, at no point in time following the filing of the government’s Complaint did Teva conduct an interview of the Witness (nor has Teva made the government aware of any interview of the Witness at any time) or seek a declaration from the Witness. Indeed, as far as the government knows, Teva *has done nothing at all* to seek to procure information from the Witness; this despite *Teva’s* request (largely granted) for an extended discovery schedule. *See* ECF No. 36. Teva had more than *two years* since the filing of the United States’ Complaint to seek information or testimony from the Witness and chose not to do so.

Not only did Teva fail to gather any evidence from this “nearly irreplaceable” witness—it put off their deposition for months when they were available. The government first requested a deposition date for the Witness on July 8, 2022. Ex. 11 (July 22, 2022 Email chain at p. 1 and 3). A week later, Teva was “still working on collecting schedules.” *Id.* at 3. On July 22, Teva’s counsel reported that “we are unlikely to be available for depositions until mid-August both based upon the witness’ schedules and my own.” *Id.* at 1. By August 1, Teva promised it would provide a date the following week. Ex. 12 (August 1, 2022 Email chain) at 2. By August 16,

Teva still had not provided a date. Ex. 13 (government’s August 16, 2022 Letter at 4). The government continued to press Teva for a date, and on September 19, Teva provided a doctor’s note stating that the Witness was able to testify for up to an hour a day. Ex. 14 (September 19, 2022 Email) at 3; Ex. 14 (attachment) at 1. Simply put, Teva put off the Witness’s deposition until the Witness eventually became unable to testify.

II. Legal Standard

The First Circuit has held that where, as here, a litigant seeks to amend after the expiration of a deadline set in a scheduling order, “Rule 16(b)’s more stringent good cause standard supplants Rule 15(a)’s leave freely given standard.” *O’Brien v. Town of Bellingham*, 943 F.3d 514, 527 (1st Cir. 2019) (quoting *United States ex rel. D’Agostino v. EV3, Inc.*, 802 F.3d 188 (1st Cir. 2015)). In the First Circuit, untimely defenses may be raised “when ‘(1) ‘the defendant asserts it without undue delay and the plaintiff is not unfairly prejudiced by any delay,’ or (2) ‘the circumstances necessary to establish entitlement to the affirmative defense did not obtain at the time the answer was filed.’” *Id.* at 528 (quoting *Davignon v. Clemmey*, 322 F.3d 1 (1st Cir. 2003)).

Undue delay occurs where a party knows the factual basis for a defense but does not assert it. *See O’Connell v. Hyatt Hotels of Puerto Rico*, 357 F.3d 152, 155-156 (1st Cir. 2004) (affirming denial of amendment five months after deadline to amend and stating that there is no good cause “where ‘information supporting the proposed amendment was available [to plaintiff] even before she filed suit’ or where party was ‘obviously aware of the claim for many months’”) (citing *Leary v. Daeschner*, 349 F.3d 888 (6th Cir.2003) and *Sosa v. Airprint Sys., Inc.*, 133 F.3d 1417 (11th Cir.1998)). Similarly, prejudice occurs where discovery has already taken place without reference to the proposed amendment. *Quaker State Oil Ref. Corp. v. Garrity Oil Co.*,

884 F.2d 1510, 1517-18 (1st Cir. 1989) (denying leave to amend with two months remaining in discovery, where “the facts upon which the proposed counterclaim rested were known to defendant all along” and “[a] great deal of discovery had taken place without reference to the neoteric theory, thus prejudicing [the opposing party].”).

The denial of a motion to amend the pleadings is reviewed for abuse of discretion and affirmed “if any adequate reason for the denial is apparent from the record.” *O’Connell*, 357 F.3d at 154.

III. Argument

Teva has failed to show good cause for its belated amendment. First, Teva’s Motion fails to identify any new or different facts relating to the advice of counsel defense that it carefully chose to forego pursuant to a specific Court order over six months ago, after years of consideration. Second, waiver and assertion of a new affirmative defense following the close of fact discovery would inherently and substantially prejudice the government. The entirety of fact discovery has been completed without any reference to an advice of counsel defense and with Teva withholding copious amounts of information on privilege grounds. Every aspect of the government’s discovery—from interrogatories, to requests for production, to depositions, and requests for admission—would have inquired into the defense and would have been done differently if Teva had invoked an advice-of-counsel defense. Under *O’Connell* and *Quaker State*, these first two considerations alone merit denial of Teva’s Motion. But other equitable considerations abound. During discovery, Teva failed to disclose any facts at all regarding the Witness’s understanding or interpretations of laws or regulations—in fact, the Witness had already testified under oath to having no recollection of any such interpretation. By failing to disclose those facts, Teva waived its right to now rely on them. Teva also engaged in extensive

delay tactics with respect to its decision on an advice of counsel defense, its production of documents, and the Witness's deposition, which the government attempted to schedule well in advance of the Witness's apparent unavailability. For months, Teva dragged its feet, often providing updates only when prompted by the government, and it appears that this delay closed a window of opportunity to obtain the Witness's testimony. Teva's reason for seeking amendment at this late juncture is precisely the type of tactical gamesmanship that courts in the First Circuit have rejected as inequitable to opposing parties.

A. Teva Has Known The Facts Underlying Its Advice of Counsel Defense For Years—And Has Identified No New Facts Concerning Such A Defense

Teva's Motion makes clear that this is not an instance where a party has uncovered new evidence regarding its attorneys' advice. On the contrary, Teva made its decision not to invoke advice of counsel after years of careful consideration and investigation, and has cited no facts relating to its advice of counsel defense that were unknown to it when it decided not to raise the defense on June 15.

Teva's consideration of its attorneys' advice began during the government's pre-litigation investigation. Teva's counsel attended interviews of numerous witnesses it represented, including the Witness (who was first interviewed in 2018). Teva repeatedly claimed privilege during those interviews. In August 2019, Teva produced a 408-page privilege log with 9,124 entries spanning a 7-year period from 2010-2017. In July 2022, Teva produced another log with 2,410 additional entries spanning a 12-year period from 2005 to 2017. Ex. 3, 7.

Once litigation began, as discussed above, Teva took twenty-two months before deciding not to invoke advice of counsel.⁴ During that time, the government served Teva with numerous interrogatories and document requests that required Teva to determine whether it was claiming the defense. Teva's counsel also represented the Witness and all current and former Teva employees that the United States deposed.

Given Teva's counsel's years-long participation in the investigation and litigation of this matter, it is not surprising that Teva cannot now point to any facts regarding advice of counsel that were unknown on June 15, when it decided not to assert the defense. Teva's sole argument is that the Witness would have testified "concerning non-privileged information"—in other words, information that was *de facto* unrelated to an advice of counsel defense. ECF No. 121 at 2-3. This is not an equitable reason to allow Teva to revisit its decision.

B. Teva's Post-Discovery Assertion Of Advice Of Counsel Would Inherently And Substantially Prejudice The Government

The parties have now completed fact discovery under the auspices of Teva's express claim that "Teva will not invoke the advice of counsel defense in this matter." ECF No. 92-6. The United States sought information from the outset of discovery that would have enabled it to fully develop the record regarding Teva's affirmative defenses, including planning for further interrogatories and to identify and effectively prepare to examine and cross-examine deposition witnesses. *See* May 19 Hearing, at 9:14-17.

For example, the government's interrogatories, served over a year ago near the outset of discovery, would have required Teva to state the basis for any such defense, including identifying all documents and communications concerning any such advice. Ex. 5 at p. 4

⁴ The government filed its Complaint on August 18, 2020 (ECF No. 1), and Teva decided not to invoke on June 15, 2022 (ECF No. 92-6).

(Interrog. 1). The government's requests for production, also served over a year ago, would have required Teva to provide all attorney communications, which the government would have used to prepare further interrogatories and RFAs and to identify and examine and cross-examine deposition witnesses. Ex. 6 at 6. Finally, the government's requests for admission also addressed Teva's understanding of the applicable law and regulations, and would have been asked (and presumably, answered) differently in the presence of an advice of counsel defense. Ex. 16, United States' First Set of Requests for Admission, at 4 (RFA Nos. 6-8).

In short, every aspect of discovery would have been done differently had Teva waived privilege and asserted an advice of counsel defense. The government anticipates that it would need substantial additional time to review and assess Teva's supplemental productions, which would include many documents from the 11,534 entries on its privilege logs.⁵ It would need to re-open depositions of current and former Teva employees, including new employees reflected in privileged documents or who received such advice who the government has not deposed. For example, Teva's counsel raised privilege objections during testimony pursuant to CIDs of witnesses who were not deposed in litigation, but who the United States might need to depose in light of an advice of counsel defense. *See, e.g.*, Jennifer Jackson CID Tr. at 43:14-16, attached as Ex. 18 (Teva's counsel: "I want to advise you not to divulge any communications you had with a lawyer."). The government also would need to depose all attorneys who purportedly provided advice concerning Teva's patient assistance programs, which, based on Teva's hundreds of pages of log entries, are legion. Some witnesses are third parties, some may require

⁵ Although Teva implies that much of the withheld information is irrelevant, that claim is belied by the logs themselves. Nearly all the entries appear to have potential relevance. For example, in the first privilege log alone, 1,531 withheld documents are described as "regarding patient assistance programs." Ex. 3.

third-party subpoenas for documents, some may now be unavailable, and all will have memories that are more stale than when discovery started in this case. In sum, granting Teva's Motion would likely require months of additional discovery that is inherently less effective than full discovery taken from the outset with the benefit of time, a complete document record, and supporting discovery requests. It also likely would delay the September 2023 trial date. It is not, as Teva erroneously suggests, a "modest" extension of the discovery schedule.⁶ ECF No. 121 at 10. In view of the full implications of Teva's request, Teva's assertion that its Motion is "not motivated by any gamesmanship" and that the government will suffer "no prejudice" (ECF No. 121 at 10) strains credulity. Indeed, viewed against the backdrop of Teva's repeated refusals to timely respond to the government's inquiries about whether it would invoke, Teva's late-breaking request to invoke the defense smacks of gamesmanship.⁷

Finally, Teva's motion makes clear that it also seeks to use selective waiver to further hamstring the government. That issue must be litigated, further delaying this matter and prejudicing the government. According to Teva, waiver should only cover 2006 to 2014—*i.e.*, excluding the initial planning of Teva's schemes, and years of contributions and communications after 2014. ECF No. 121 at 7 (waiver should apply to "advice Teva sought and received concerning the lawfulness of its donations to copay assistance funds for Medicare Part D patients from January 1, 2006, through December 31, 2014). More importantly, Teva's Motion appears

⁶ Teva's characterization of the "modest" additional discovery necessary to investigate its advice of counsel defense is also belied by what Teva told the Court when it was seeking to delay the deadline to determine whether to invoke the defense. At that point, Teva claimed that it had "undertaken a significant investigation to date" as they were "dealing with an issue that has been within the company dating back 16 years." May 19 Hearing at 7:1; 7:5-6.

⁷ The government also notes that Teva requested and largely received a more extended discovery schedule than the government sought (ECF No. 36), and yet still Teva could not bring itself to decide to seek to invoke the defense until November 2022, more than two years after the government filed the Complaint.

to take the nonsensical position that waiver should extend only to communications with the Witness, and not to other Teva employees who may have received advice. ECF No. 121 at 3 (stating that Teva will be hindered “without waiving the attorney-client privileged advice [the Witness] received concerning Teva’s Medicare donations during [the Witness’s] tenure.”). There is no basis for this position. *See Bacchi v. Mass. Mut. Life Ins. Co.*, 110 F. Supp. 3d 270, 275 (D. Mass. 2015) (“[F]airness dictates that the opposing party should be able to discover *all* of the attorney’s communications on the particular subject, not just the advice that is helpful to the defendant.”) (emphasis added) (internal citation omitted). Should the Court permit Teva to invoke, the government will oppose Teva’s self-serving, and legally unsupportable, selective waiver proposal, necessitating further motion practice and further delay of the trial in this matter, causing further prejudice to the government.

The cases Teva relies upon do not support its argument that the government would suffer no prejudice. For example, Teva cites *United States ex rel. Hockaday v. Athens Orthopedic Clinic PA*, 2021 WL 5015616, No. 3:25-cv-122 (CDL) at *2 (M.D. Ga. Oct. 27, 2021) as an example of a court holding that additional discovery did not prejudice the opposing party. But that case apparently involved advice of counsel provided by a single attorney—unlike here, where Teva has withheld 11,534 documents from many attorneys. *Id.* at *2. Also unlike the present case, the court found that due to other delays and its post-COVID trial schedule, there was “plenty of time” for the parties to complete discovery without moving the trial date. *Id.* Teva similarly relies on *LG.Philips LCD Co. v. Tatung Co.*, 243 F.R.D. 133 (D. Del. 2007), a patent case in which the parties were still completing outstanding fact discovery and the court found that just one additional month would be sufficient to complete discovery on the advice of

counsel issue. *Id.* at 138-139.⁸ By contrast, as described above, if the Court permits Teva to invoke now, the government would have to conduct *substantial* additional discovery.

C. Teva Never Disclosed The Hypothetical Facts It Now Claims It Was Relying On

Teva argues that when it decided not to invoke advice of counsel, it “anticipated that its affirmative defenses for the 2006 to 2014 time period would be supported by the testimony of [the Witness]....”; that the Witness was prepared to testify concerning “*non-privileged* information [they] considered and relied upon in making the donations that are the subject of this litigation”; and that “Teva, through [the Witness], believed and understood . . . that Teva’s patient assistance program for Medicare-eligible patients with MS complied with federal laws and regulations and were in accordance with applicable agency documents, such as the OIG’s 2005 SAB and 2014 Supplemental Special Advisory Bulletin. . . .” ECF No. 121 at 8 (emphasis added). But if any of that is true, Teva failed to disclose it in interrogatory responses that it served a week *after* it decided not to invoke advice of counsel, and that required it to state the basis for the specific defenses now at issue.

The government’s Interrogatory No. 16 required Teva to “State the basis for Teva’s assertion that ‘Teva’s actions were based on an objectively reasonable interpretation of the guidelines established by the OIG[.]’ (Answer, p. 28).” Ex. 5, United States’ Second Set of Interrogatories, at 3. Similarly, Interrogatory No. 17 required Teva to “State the basis for Teva’s

⁸ The *LG.Philips LCD* court was also persuaded by the fact that under the substantive law of willful infringement, reliance on competent advice was a factor to be considered in determining the plaintiff’s claim of willful infringement. *LG.Philips LCD* at 136-137 (“[T]he Court is foremost guided by the substantive law concerning willful infringement. Whether an accused infringer acted willfully is a question of fact determined in light of the totality of the circumstances concerning the alleged infringer’s state of mind. . . . Reliance on the competent advice of counsel as a means of showing a party’s good faith is but one factor relevant to this determination.”).

assertion that ‘Teva’s actions were undertaken in good faith and/or in reasonable reliance upon regulatory interpretations, judgments or other statements by federal employees or officials upon whom Teva was entitled to rely.’ (Answer, pp. 27, 30).” *Id.* Local Rule 26.5(c)(8) defines “State the Basis” to require a party to disclose “each and every communication” and to “state separately any other fact which forms the basis of the party’s information regarding the alleged facts or conclusions referred to in the interrogatory.” *Id.* The government served these interrogatories three weeks before Teva’s deadline to invoke an advice of counsel defense. Ex. 19, United States’ Second Set of Interrogatories, at 3.

Nowhere in Teva’s response did it disclose anything remotely resembling the testimony or facts that it now claims the Witness would assert. After a paragraph of objections, Teva’s response (it issued a single response for both interrogatories) makes reference to unidentified and uncited government documents. Ex. 1, Teva’s Responses and Objections to United States’ Second Set of Interrogatories at 8-9. It then characterizes the 2005 HHS-OIG guidance document. *Id.* Nowhere in the response does Teva discuss the Witness, or *anyone* at Teva who allegedly held any interpretations of the documents discussed, had ever seen any of these government documents, or held any particular view or interpretation of any rules or documents. *Id.* Nowhere did Teva disclose that the Witness “believed and understood” the facts that Teva’s counsel now claims.

In fact, the “anticipated” testimony never existed. In the Witness’s sworn CID testimony, the Witness flatly contradicted Teva’s current claim that the Witness *would* have testified to an understanding that Teva’s patient assistance programs complied with the OIG’s 2005 SAB and 2014 Supplemental Special Advisory Bulletin:

Q: Did you ever look at the 2005 Special Advisory Bulletin that HHS OIG put out about special -- about co-pay foundations?

A: **I don't recall.**

[..]

Q: Were you aware that HHS OIG had cautioned pharmaceutical companies about correlating the amount or frequency of their donations with the amount or frequency of the use of their products?

A: **I -- I don't recall**

[...]

Q. Did you have any understanding of cautionary language that HHS OIG had issued concerning co-pay foundations?

A. Specifically with regard to HHS -- HHS OIG opinions?

Q. Or any other? Did you have any understanding of the rules of the road with respect to co-pay foundations and how pharmaceutical companies should deal with them?

A. My understanding was that we should not -- we should not do a -- an ROI.

Q. What's an ROI?

A. Return on investment.

Q. What's your understanding of why pharmaceutical companies should not do an ROI?

A. Because we didn't correlate -- or it's not an investment, it was a contribution, and it was treated as a contribution.

Q. Beyond a prohibition on doing ROI's, did you have any understanding of the rules concerning how a pharmaceutical company should deal with co-pay foundations?

A. **I don't remember.**

Ex. 20, Excerpt from June 11, 2019 CID Tr. of Witness, at 91:4 – 92:21 (emphases added).

Simply put, Teva has not shown any undue prejudice from the self-imposed lack of testimony from a witness who has already contradicted, under oath, the very claims that Teva baldly asserts they would have made during a deposition or at trial.

D. Teva Engaged in Undue Delay

In assessing the balance of equitable considerations, courts also look to whether a party has engaged in undue delay. *Aoude v. Mobil Oil Corp.*, 892 F.2d 1115, 1121 (1st Cir. 1989). Teva engaged in serial delays with respect to this issue, all of which weigh against a belated amendment.

First, Teva unduly delayed its original decision *not* to invoke advice of counsel. *See supra* at Section I. Sixteen months after the Complaint was filed, Teva committed to decide within *another* six months, by May 19, 2022. ECF No. 50 at 1. When Teva failed to do so, the government was forced to bring the issue before the Court, upon whose order Teva finally stated that it was not invoking advice of counsel. This undue delay put off depositions—including the Witness’s deposition—for months. Had Teva decided within any reasonable length of time, it would not find itself in its current (purported) bind.

Second, Teva unduly delayed producing documents pursuant to the government’s document requests. *See supra* at Section I. As described above, Teva did not finish its production until ordered by the Court, unsuccessfully challenged the Court’s imposition of a deadline, and finally produced 73,707 documents 8 months after the government served its document requests. This production schedule delayed depositions, including that of the Witness. May 19 Hearing at 9:14-17.

Third, Teva delayed in gathering any of the hypothetical facts it now claims were critical to its defenses. Teva’s counsel has represented the Witness for over four-and-a-half years, since the government interviewed the Witness on April 30, 2018. During those four-and-a-half years, during more than two years of litigation, and a year of fact discovery, Teva never took the Witness’s deposition nor, apparently, memorialized any evidence at all from the Witness to support the claims it now makes in the Motion.

Finally, Teva put off the Witness’s deposition for months while the Witness was still available. *See supra* at Section I. As described above, the government first requested a deposition date for the Witness on July 8, 2022. Teva dragged its feet in scheduling the deposition. The Witness was still available as recently as September 15, 2022—two months after the government first sought to take the Witness’s deposition. Had Teva scheduled the deposition without undue delay—even *two months* after the government requested a date—it would have avoided its claimed problem.

As a result of its delay, any prejudice to Teva is of its own making; therefore, it is not a cognizable reason for a belated amendment. *See, e.g.,* Ex. 21, January 8, 2016 Hr’g Tr. in *United States ex rel. Kieff v. Wyeth*, 03-CV-12366-DPW (D. Mass. 2003), at 49:10-19 (Judge Woodlock, in considering an attempt to invoke advice of counsel after the close of discovery, stating: “I view [this] as the ultimate in gamesmanship. . . . It was an important decision to assert the attorney-client privilege. It does not get changed at the last minute.”); *Minter v. Prime Equip. Co.*, 451 F.3d 1196, 1211 (10th Cir. 2006) (“Whatever harm befalls [defendant] as a result [of its decision early in litigation that it would not assert a particular claim] is of its own making, and therefore does not qualify as prejudice under Rule 15(a).”).

The case Teva cites to support its claim that it “has not dragged its feet” in fact undercuts that assertion. *See* ECF No. 121 at 10 (citing *Penobscot Nation v. Mills*, 2014 WL 442429, No. 1:12-cv-254-GZS, at *3 (D. Me. Feb. 4, 2014)). In *Penobscot*, defendants filed their motion to amend *eight months* prior to the discovery deadline. *Id.* at *3 (noting motion filed August 26, 2013, and discovery deadline was April 21, 2014). The court also noted that the proposed affirmative defense—failure to join an indispensable party—was apparently supported by a letter that the *opposing party* had recently written. *Id.* By contrast, here, fact discovery is completed,

and Teva has long known the facts underlying its advice of counsel defense—all of which were within its possession throughout this case.

IV. Conclusion

For these reasons, the Court should deny Teva's Motion.

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Respectfully submitted,

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